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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,001	04/07/2004	Peter Palese	NS104D1C1	9293
36577	7590	09/11/2006	EXAMINER	
JOHNATHAN KLEIN-EVANS ONE MEDIMMUNE WAY GAITHERSBURG, MD 20878			GARVEY, TARA L	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



## **DETAILED ACTION**

Claims 80-96 are pending. Receipt is acknowledged of an amendment filed on March 2, 2006 in which claims 1-79 were canceled and new claims 80-96 were added.

### ***Response to Amendment***

#### **Claim Objections**

The objection of claims 35-37 is moot in view of cancellation of the claims.

#### **Claim Rejections - 35 USC § 102**

The rejection of claims 35-48 under 35 U.S.C. 102(e) as being anticipated by Palese et al (U.S. Patent No. 6,544,785 B1) is moot in view of cancellation of the claims.

The rejection of claims 49-79 under 35 U.S.C. 102(e) as being anticipated by Palese et al (U.S. Patent No. 6,649,372 B1) is moot in view of cancellation of the claims.

The rejection of claims 35-48 under 35 U.S.C. 102(a) as being anticipated by Palese et al (U.S. Patent No. 6,544,785 B1) is moot in view of cancellation of the claims.

The rejection of claims 49-79 under 35 U.S.C. 102(a) as being anticipated by Palese et al (U.S. Patent No. 6,649,372 B1) is moot in view of cancellation of the claims.

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Double Patenting

The rejection of claims 35-48 under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 4-5, 7-11, 13-16, and 18-19 of prior U.S. Patent No. 6,544,785 is moot in view of cancellation of the claims.

The rejection of claims 49-79 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3, 6-7, 9, 11-12, 16-17, 19-23, 25-28, 30-32, 38-41, 43, 45-47, and 49 of prior U.S. Patent No. 6,649,372 is moot in view of cancellation of the claims.

***New Grounds of Rejection***

The new rejections were necessitated by applicant's amendment of the claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 80 is rejected under 35 U.S.C. 102(a) as being anticipated by Luytjes et al (Cell (1989) volume 59, pages 1107-1113; cited in the IDS submitted October 18, 2004).

Claim 80 is drawn to a composition comprising influenza virus particles that comprise a recombinant vRNA segment.

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Luytjes et al teaches a recombinant influenza virus particle that has the coding sequence of the influenza A virus NS gene replace with a chloramphenicol acetyltransferase gene. The influenza virus is produced from a recombinant RNA, which reads on a vRNA because the CAT gene was inserted into the viral RNA sequences for the NS gene segment (abstract, page 1107, right column, second full paragraph, page 1108, Figure 1 and page 1110, right column and page 1111, left column, third full paragraph). Thus, Luytjes et al teaches all that is recited in the instant claim.

Claims 80, 83 and 84 are rejected under 35 U.S.C. 102(a) as being anticipated by Enami et al (PNAS (1990) volume 87, pages 3802-3805; cited in the IDS submitted October 18, 2004).

Claims 80, 83 and 84 are drawn to a composition that comprises an influenza virus particles that comprise a recombinant vRNA segment, which encodes a neuraminidase (NA) protein and the NA protein is modified.

Enami et al teaches an infectious influenza virus that comprises a point mutations that were made in the NA gene from isolate viral RNA. The influenza virus is produced from a recombinant RNA, which reads on a vRNA segment because the RNA for the NA gene segment was isolated from a virus and then modified to produce a recombinant influenza virus (abstract, page 3803, right column to page 3805, left column).

***Double Patenting***

Claim 80 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 47 of U.S. Patent No. 6,649,372. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to a composition of comprising a recombinant influenza virus that has a recombinant vRNA segment.

Claims 80, 90, 91 and 96 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 23-28 and 45-48 of copending Application No.10/713,732 (US 2004/0109877). Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets encompass a composition of recombinant attenuated influenza viruses that are mutated in the NS1 gene of the viral genome, which reads on a recombinant vRNA segment that encodes an NS1 protein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Allowable Subject Matter***

Claims 81-82, 85-89 and 92-95 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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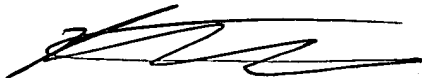
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Tara L Garvey, Ph.D.  
Examiner  
Art Unit 1636

TLG

SELINE GIAN, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'S. Gian', written over the printed name of the primary examiner.